**PATENT** 

# HEAD SUPPORT DEVICE FOR USE WHEN LYING IN THE PRONE POSITION BACKGROUND OF THE INVENTION

Field of the Invention:

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The present invention relates to a head support device, such as a headrest or pillow, which provides comfortable facial support while the user is lying face down. More particularly, the head support apparatus is adapted to minimize contact with the user's face while concurrently cushioning the forehead, cheek and maxillary areas of the user's face as well as provide an unrestricted air passageway for breathing.

## 10 Background of the Invention:

Pillows, head support devices, mattresses have been developed and described in various literature for a variety of applications and particularly addressing a person lying face down or in the prone position. There are a variety of circumstances where a person desires or is required to lie face down, such as for example, during certain types of medical procedures, sunbathing, tanning, physical therapy, massage, or sleeping.

One problem associated with lying in the prone position and using a normally flat pillow is the restriction of air passage to the person. Generally, the user must either arch their head above the surface of the pillow or turn their head to one side to breath. Arching the head results in undesirable and unnatural forces on the spine which may create reduced comfort or possible harm to the spine. However, if the user turns his or her head to breath and lies in this position, the neck must be turned at an acute angle that invariably causes increased pressure on the structures that support and comprise the neck anatomy, such as the discs, joints, muscles, and ligaments of the upper spinal column.

To address these problems, pads or pillows have been designed to incorporate an air flow passage as well as variations for facial support. For example, U.S. Patent No. 2,688,142 to E.V. Jensen describes an inflatable cushion having top and bottom cushion elements affixed to a rigid base plate. A pair of bar-like members connect facing end portions of the top and bottom cushions. The width of the bottom cushion is less than the width of the top cushion which results in a shape generally in conformity with the shape of the face of the user. When used, the top cushion supports the user's forehead, the bottom cushion supports the user's chin and the side bar cushions engage the sides of the mouth, nose and eyes of the user. However, a problem with the support device described in U.S. Pat. No. 2,688,142 is that a substantial amount of pressure is exerted on the user's chin, which is in turn translated to the mandible, which over time can cause misalignment of the jaw.

U.S. Patent No. 3,312,987 to W. M. Emery describes an cushion having inflatable inner bladder, an intermediate polyester foam sleeve that at least partially encloses the bladder, and a contoured cover that restricts the expansion of the bladder and maintains a wrinkle free tautness for a smooth facial contact. The improvement of this support over other similar support devices was that the intermediate polyester foam sleeve provided space for the bladder to expand into when used while still allowing the cover to remain taut.

U.S. Patent No. 3,337,883 to J. D. Allison describes a headrest capable of supporting the head and cervical spine of a patient while lying in the prone position for treatment to the posterior cervical or thoracic area. The headrest includes a concave trough-shaped support having a cut-away central portions to accommodate the eyes, nose, and mouth of the patient. A pad of soft foam lines the inner surface of the support which

provides support for the forehead, maxillary areas, chin and lateral borders of the face. The body is supported by a pair of leg panels which are integrally secured to the concave body. The leg panels extend downwardly sufficiently below the body to provide adequate clearance for the nose. The lower surfaces of the leg panels are rounded to permit the head rest to rock front to back. Extending outward from the leg panels is a pair of bearing flanges for increasing the area of contact between the head rest and the supporting surface.

U.S. Patent No. 5,269,035 to Hartunian describes a head support device for supporting a patient's head and neck during surgery. The support device is generally composed of three rectangular cubic connected members having the appearance of a "U" lying on its side. The top and bottom members have an arcuate shaped cavity for receiving the forehead and chin of the patient. There is an opening in the middle of the side member for accommodating the needs of an anesthetist. However, Hartunian teaches that it is critical that the head support device support only the forehead and chin of the patient.

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U.S. Patent No. 5,546,619 to Braun describes a rigid head support device for use while sun tanning or sunbathing. The head support device includes a rigid horseshoe-shaped head support member having a plurality of pivotal supporting legs attached to the bottom wall of the head support member. Covering the rigid support is a layer of cushioning. One problem with the design described by Braun is that the supporting legs are of equal height. Thus, when the legs are placed on a surface that is sufficiently firm, the user will have an unequal degree of pressure exerted over the user's contact region with the cushion.

U.S. Patent No. 5,970,546 to Danis describes a portable headrest for sunbathing having a generally an inverted U-shaped configuration head support member. The head support member includes an outer material covering, an internal foam support cushion and a rigid support base plate. The rigid support base member has a generally curved-shaped configuration for providing a stable support on sand, soft ground, or grass. A plurality of spaced-apart connecting members connect the head support member to the base support member and define a plurality of air passageways between the bottom of the head support member and the top of the base support member for allowing air to the user's face when the user is lying in the prone position.

U.S. Patent No. 6,230,350 to Goldstein describes a support pillow for cushioning the head of a person lying face down. The pillow includes an air recess that extends through the support pad from the upper surface to the lower surface and an air flow conduit that extends from the face recess through the body of the support pad to the exterior to provide fresh air to the face recess area. The air flow conduit contains a rigid support member to prevent the conduit from being compressed, restricted or closed by the weight of the user's head and a filter to block particulate matter from entering the air flow conduit.

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U.S. Patent No. 6,374,441 to Begell describes headrest having a substantially "U" shaped configuration contoured for receiving and supporting a user's head when lying in the prone orientation. A dense foam cushion is contoured to the shape of a person's facial bones to support the user's face by direct engagement with the person's face, decreasing the pressure particularly in the area of the frontal sinus and maxillary sinus cavity and facial bones, specifically the bony area around and under the eye (zygomatic bone), by increasing the surface area contacting these areas. A central opening through the cushion,

angled in from the contact locations, receives the nose and mouth portions of the user's face and permits breathing.

International application no. WO 97/43933 describes an inflatable inverted "U" shaped head support device made from at least two layers of a web material welded together and having an intermediate material between the two legs of the inverted "U". However, this device would not be suitable for supporting a user's head when lying in the prone position since the intermediate material would interfere with the user's breathing.

Japan publication 7275098 discloses an inverted "U" shaped head support device cushion composed of a soft material such as a foam or sponge. The user rests his or her head on the upper portion of the inverted "U" with the rods or legs of the inverted "U" supporting the cheek region of the user. The cushion is supported by a rigid plate or skeleton that is provided with holes for ventilation.

From the above it can be appreciated that there still exists a need for a padded head rest or support which can be used primarily for supporting a user's head while lying in the prone position. The head support device of the present invention substantially departs from the aforementioned concepts and designs which provides a stable and comfortable head rest having unimpeded air passage for the user's breathing.

#### SUMMARY OF THE INVENTION

Briefly, the present invention is a head support device, such as a headrest or pillow, which provides comfortable facial support while the user is lying face down in the prone position. The head support device has a cushion or padded member for contacting and supporting the user's facial region. The padded member is generally horseshoe-shaped

having a curved upper area for contacting a user's forehead; gently arcuate sloping sides terminating at distally located spaced apart ends.

The padded member is supported by a substantially rigid support member. The support member includes a plurality of predetermined regions or zones adapted for engaging the padded cushion and to provide comfortable support to predetermined facial areas of the user. The support member is generally configured in a modified "V" or "U" shape where the upstanding portions are splayed outward relative to vertical so as to provide a breathing air access channel for the free exchange of air when the user inhales or exhales. As viewed from the side, the support member has a gentle incline that rises from a first end of the support member to a distal second end to provide a steady elevation and comfortable support for the user's head and neck while the user is lying in the prone position.

It is an object of the present invention to provide a comfortable headrest or support device having a padded member for receiving and cushioning the user's face and a substantially rigid support member for supporting the padded member and providing an unobstructed air passageway for easy communication of fresh air to the user when lying in the prone position.

It is another object of the invention to provide a comfortable headrest or support device wherein the substantially rigid support member has a sufficiently large base surface area so as to prevent sinking of the support into sand, soft ground, or grass when the user is lying in the prone position.

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Another object of the invention to provide a comfortable headrest or support device wherein the substantially rigid support member additionally provides support and stability

to substantially prevent lateral movement of the headrest device in sand, soft ground, or grass.

Another object of the present invention is to provide a headrest having an outer material covering of the upper padded member that is durable in use, easily washed, rinsed and sanitized for repeated use by the user.

These and other objects and advantages of the present invention will become more apparent to those skilled in the art in view of the following description and the accompanying drawings wherein like parts and objects have similar reference numerals. It is to be understood that the inventive concept is not to be considered limited to the constructions disclosed herein but instead by the scope of the appended claims.

## BRIEF DESCRIPTION OF THE DRAWINGS

- FIG. 1 is a perspective view of the head support device of the invention illustrating a padded member for engaging the user's facial region supported by a substantially rigid support member.
- FIG. 2. is an exploded view of the head support device of the invention showing in greater detail specific regions of the rigid support member that are adapted to receive certain areas of the user's face and means for attaching the padded member to the substantially rigid support member.
- FIG. 3 is a cross-sectional view taken along line 3--3 of FIG. 1.

- FIG. 4 is a cross-sectional view taken along line 4--4 of FIG. 1.
- FIG. 5 is a cross-sectional view taken along line 5--5 of FIG. 1.
- FIG. 6 is a perspective view of an alternative embodiment of the substantially rigid support member.

### DETAILED DESCRIPTION OF THE INVENTION

By way of illustration and not limitation, the present invention will be described in greater detail with reference to FIGS. 1-6 as preferred embodiments of the present invention. Referring to FIGS. 1-5, a head support device 10 for supporting a user's head while lying in the prone position is illustrated. The headrest or head support device 10 has a cushion or padded member 12 for contacting the user's facial region. The padded member 12 is generally horseshoe-shaped and has a top 14, gently arcuate sloping sides 16, and distally located spaced apart ends 18.

The general horseshoe-shape of the padded member 12 allows the passage of air to the user's face when the user is lying in the prone position. The horseshoe-shaped padded member 12 has a top surface 20, a bottom surface 22, an outer side wall 24, a first inner side wall 26 and a second inner side wall 28. The first inner side wall 26 and the second inner side wall 28 are spaced apart sufficiently so as to define the open area for the user's breathing.

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Referring to FIGS. 1 and 3-5, the padded member 12 includes at least three areas or regions: a first or upper region 30, a second or middle region 32, and a third or end region 34, which are contoured and adapted to contact and comfortably support the user's head. Desirably, the three regions are contiguous such that the first region 30 extends from the top of the middle region 32 to the top 14 of the padded member 12. The first region 30 is adapted to support the user's frontal sinus or forehead area. As seen in FIG. 3, the upper region has a width "d" ranging from about 5 centimeters (cm) to about 20 cm, preferably from about 5 to about 15 cm, and more preferably from about 6.25 cm to about 11 cm. The width of each region 30-34 is determined at the widest point between the first inner side wall 26 and a second inner side wall 28.

The second or middle region 32 extends from the top of the third or lower region 34 to the bottom of the first or upper region 30. The middle region 32 is adapted to support the user's facial bones, from just above but out to the side of the eye socket bone to just below the maxillary bone of the user. As seen in FIG. 4, the middle region 32 has a width "e" ranging from about 5 cm to about 30 cm, preferably from about 5 cm to about 17 cm and more preferably from about 7.5 cm to about 17 cm.

The third or lower region 34 extends from the bottom of the middle region 32 to the spaced apart ends 18. The lower region 34 is adapted to support the sides of the user's mandible. As seen in FIG. 5, the lower region 34 has a width "f" of from about 1.4 cm to about 8 cm, preferably from about 1.4 cm to about 8 cm, and more preferably from about 2.5 cm to about 6 cm. By using such facial contours, the headrest of the present invention increases the surface area contacting specific areas of the face while the user is in the prone position. Advantageously, by supporting these areas and particularly the lower mandible, the head support 10 substantially reduces the detrimental effects of the earlier described devices by avoiding direct frontal pressure on the chin, thereby substantially increasing user comfort over pillows or other head support devices of the prior art where such frontal pressure may, over time, cause user discomfort or jaw misalignment.

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The padded member 12 includes an inner core 36 sheathed in an outer covering 38.

The inner core 36 can be composed of a variety of natural and synthetic materials.

Suitable materials for constructing the inner core 36 include a foam material, for example, foam rubber, rubber-latex foams, open-cell or closed-cell foams, polyurethane, polyethylene, and polyvinyl foams. Slight resiliency of the foam material is preferred, but not essential. Desirably, the inner core 36 is composed of a material that displays a degree of fluidity. As used herein "degree of fluidity" means that material will undergo a

change in at least one attribute selected from density or volumetric displacement when a substantially vertical load of more than 100 grams is placed on the inner core 36. For example, expanded polymer foams, air, liquids, gels, air-gel filled bladders, polymeric beads, loosely compacted polymeric fibers such as POLYFIL and combinations of these materials would meet this definition.

The inner core 36 has an average thickness of from about 1 cm to about 12 cm, preferably from about 1 cm to about 8 cm, and more preferably from about 1.5 cm to about 5 cm. In a preferred embodiment, the thickness of the inner core 36 varies over the length of the padded member 12 such that the padded member 12 is relatively less thick at the ends 18 than at end 14. Accordingly, the lower region 34 has an average thickness "T<sub>1</sub>" of from about 1 cm to about 5 cm, preferably from about 1 cm to about 4 cm and more preferably from about 1 cm to about 3 cm; the middle region 32 has an average thickness "T<sub>2</sub>" of from about 1.5 cm to about 7 cm, preferably from about 1.5 cm to about 5 cm and more preferably from about 2 cm to about 3.8 cm; and the upper region 30 has an average thickness "T<sub>3</sub>" of from about 2.0 cm to about 10 cm, preferably from about 2.5 cm to about 8 cm and more preferably from about 2.5 cm to about 5 cm.

The outer covering 38 can be made from a variety of covering materials known to those skilled in the art. For example, the outer covering 38 can include natural and synthetic material selected from vinyl, rubber, leather, cotton, nylon, rayon, polyester, neoprene, and combinations of two or more of these materials. Combinations of materials can include woven or non-woven webs, blends and multi-layer coverings wherein the layers may be individually identifiable or may be laminated together. Desirably, the outer covering is a multi-layer, pliable material having a soft hand exterior surface for contacting the user's skin and a moisture resistant or impermeable inner surface for

isolating the inner core 36. Suitable materials include a woven polyamide having a rubberized backing available from Stafford Textiles, Ltd., Toronto, Canada sold under the trade name SOFLUX LVT. Whatever the material used, it should provide a soft, nonabrasive cushion for the user.

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The outer covering 38 encapsulates or encloses the inner core 36 using methods known to those skilled in the art. For example, the outer covering 38 can be a single piece of material which is folded over and the edges secured together to encapsulate the inner core. Alternatively, a strip of outer cover material having a width of from about 0.5 cm to about 4 cm wide which can be wrapped around the inner core 36 which is then affixed to the inner core 36 at a terminating location, such as at one of the ends 18.

Another alternative is for the outer covering 38 to be a plurality of pieces that are secured together so as to encase the inner core 36. For example, the outer covering 38 can be two individual halves of a pattern. The inner core 36 may then be placed between the two halves and the halves joined together using techniques known to those skilled in the art, such as sewing, heat sealing, ultrasonically sealing, using an adhesive, and the like.

The padded member 12 has a length, "L", that is sufficient to engage and support the user's face while lying in the prone position in the manner described herein.

Generally, the padded member 12 has a length of from about 12 cm to about 45 cm, preferably from about 12 cm to about 40 cm, and more preferably from about 15 cm to about 30 cm.

Referring to FIGS. 1-6, the padded member 12 is supported by a substantially rigid support member 50. The support member 50 is generally configured in a modified "V" or "U" shape having upstanding walls 52 and 53 outwardly splayed relative to vertical so as to define a breathing air access channel 54. As used herein, the term "substantially

rigid" means that the upstanding walls 52 and 53 will deflect less than about 40%, preferably less than about 30%, and more preferably less than about 25% when placed under a vertical load of 100 grams.

The support member 50 has a first end 56 that is positioned to reside adjacent to ends 18, a distal second end 58 that is positioned to reside adjacent the top 14, an upper surface 60 adapted to receive the padded member 12, a lower surface 62, a left perimeter 64, a right perimeter 66, a front perimeter 68 and a rear perimeter 70. The breathing air access channel 54 extends from the first end 56 to the second end 58 of the support member 50 and has a width that is sufficient for freely exchanging air as the user inhales and exhales. The channel 54 can have a width of from about 1 cm to ábout 10 cm and preferably is from about 2 cm to about 8 cm. Advantageously, the walls 52 and 53 provide a barrier to possible air contaminants that could be inhaled from the sides if the support member 50 was placed in a soft or granular surface such as sand.

Referring to FIGS. 1-5, the support member 50 includes a plurality of stabilizing members 72 extending vertically from the lower surface 62 to the bottom of channel 54. A stabilizing member 72 extends transversely from the left perimeter 64 to the right perimeter 66. It is to be recognized that the stabilizing member 72 can be positioned so that it is located even with, inside of, or extend outward from the perimeter 64, 66, 68 and 70.

The support member 50 has a height " $h_1$ " at the first end 56 of from about 1 to about 6 cm, preferably from about 1.5 cm to about 4 cm and more preferably from about 2.25 cm to about 4 cm, wherein the height of the support member 50 is measured at the bottom of a stabilizing member 72 to the upper surface 60. The support member 50 has a height " $h_2$ " at the second end 58 of from about 2 to about 10 cm, preferably from about 3

cm to about 8 cm and more preferably from about 3 cm to about 6.5 cm. It is important to the present invention that there is a sufficient height differential from  $h_1$  to  $h_2$  so that the plane of the upper surface 60 relative to the horizontal plane of the surface on which the support member 50 rests has an angle " $\theta$ " of from about 3° to about 12°, preferably from about 5° to about 10° and most preferably about 7°.

The support member 50 has a length and width that is sufficient to support the padded member 12 when the user is lying face-down on head support device 10 and has a sufficient surface area to prevent the support device 10 from sinking into sand or soft ground when being used. Generally, the support member 50 has a length, as measured from the front perimeter edge 68 to the back perimeter edge 70, of from about 12 cm to about 45 cm, preferably from about 12 cm to about 40 cm, and more preferably from about 15 cm to about 30 cm. The support member 50 has a width, as measured from the left perimeter edge 64 to the right perimeter edge 66, of from about 4 cm to about 30 cm, preferably from about 8 cm to about 20 cm and more preferably from about 12 cm to about 18 cm.

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Referring to FIGS. 1-5, each wall 52 and 53 of support member 50 further includes on the upper surface 60 a plurality of opposing, substantially parallel zones adapted to receive the padded member 12 and provide comfortable support to the facial contours of the user when lying face down on the support device 10. Each wall 52 and 53 includes a top zone 76, middle zone 78 and an end zone 80. Since the respective zones are similar for each side or wall of the support device 50, only zones 76, 78 and 80 along wall 52 will be described for brevity. The top zone 76 is positioned adjacent to the second end 58. The top zone 76 has a generally horizontal surface that is contoured for comfortably supporting the forehead of the user. The top zone 76 has a length of from about 3 cm to

about 9 cm, preferably from about 4 cm to about 8 cm and more preferably from about 4 cm to about 6 cm. The top zone 76 has a width of from about 1 cm to about 5 cm and preferably is from about 1.5 cm to about 3 cm. The top zone 76 may be positioned even with or desirably inward from the left perimeter edge 64 and back perimeter edge 70.

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The middle zone 78 is positioned adjacent to the top zone 76 and is contoured for comfortably supporting the lateral portion of the user's face, desirably adjacent to, but not on, the user's eye socket. The middle zone 78 has a length of from about 3 cm to about 20 cm, preferably from about 6 cm to about 15 cm and more preferably from about 6 cm to about 10 cm. The middle zone 78 has a width of from about 1 cm to about 9 cm and preferably is from about 3 cm to about 6 cm. The middle zone 78 may be positioned even with or desirably inward from the left perimeter edge 64. An important feature of the present invention is that the middle zone 78 has a slight concave curvature that provides a lower angle of declination along the wall 52 to the channel 54 relative to the angle of declination of the top zone 76 along the wall 52 to the channel 54. Desirably, the angle of declination is from 15° to 85°, preferably from 15 to 65° as measured from the middle of the channel to the perimeter edge 64. The slight concave curvature provides support to the padded member 12 along the middle region 32 and allows for cheek bone to be recessed below the top surface 20 of the padded member without resting on the support member 50. This provides a substantially more comfortable head support compared to the prior art headrest devices.

The end zone 80 is positioned adjacent to the first end 56 of the support member 50.

The end zone 80 has a generally horizontal surface that is contoured for comfortably supporting the lateral portion of the user's face from just below the maxillary bone and desirably along the side of the user's mandible. An important feature of the present

support device is that the end zone 80 avoids placing direct frontal pressure on the user's chin so as to prevent translating this direct force, as with other prior art devices, to the jaw joint; thereby reducing stress and possible misalignment of the joint. The end zone 80 has a length of from about 3 cm to about 9 cm, preferably from about 4 cm to about 8 cm and more preferably from about 4 cm to about 6 cm. The end zone 76 has a width of from about 1 cm to about 5 cm and preferably is from about 2 cm to about 4 cm. The end zone 80 may be positioned even with or desirably inward from the left perimeter edge 64 and front perimeter edge 68.

Referring to FIG. 6, an alternative embodiment of the rigid support member 150 is shown. Support member 150 is substantially similar to support member 50 except for the absence of the plurality of stabilizing members. To stabilize the supporting device 10, the channel 54 of the support member 150 has a substantially flat bottom 156. The length and width of the channel 54 is sufficient for freely exchanging air as the user inhales and exhales and the substantially flat bottom 156 has sufficient surface area to prevent lateral movement of the support device 10 as well as prevent the support device 10 from sinking into sand or soft ground when the user is lying face-down on the support device 10. In a preferred embodiment, the substantially flat bottom 156 has a width of from about 1 cm to about 10 cm, preferably is from about 2 cm to about 8 cm and more preferably from about 3 cm to about 6 cm. Desirably, the substantially flat bottom 156 extends the length of the channel 54, i.e., from the first end 56 to the second end 58 of the support member 150.

The support members 50 and 150 can be constructed from any substantially rigid material including resins; heat moldable plastics; light weight metals, such as aluminum; wood products such as plywood or a composite chip board, and combinations thereof.

The only requirement is that the material have a sufficiently high strength to weight ratio to prevent collapsing, breaking, or otherwise failing when placed under normal loads during the intended use. Since the support members 50 and 150 are similar, except for the differences discussed above, only support member 50 will hereafter be discussed in greater detail for the sake of brevity. Desirably, the support member 50 is made from a resin or heat moldable plastic. Preferably, the support member 50 includes a resin and most preferably includes a resin reinforced with at least one reinforcing material selected from glass, graphite, polymers such as polyamides, polyesters, polycarbonates and mixtures thereof. The reinforcing material can be in the form of flakes, fibers, mats, webbing, mesh or a combination thereof. The reinforcing material may be randomly orientated or positioned in a predetermined pattern in the resin. Desirably, the support member 50 is a glass web or mesh reinforced resin that is molded in a predetermined shape using techniques known to those skilled in the molding arts.

Referring to again to FIG. 2, the padded member 12 is affixed support member 50 by the attachment means 200. The attachment means 200 can be any means known to those skilled in the art for affixing two materials together. The manner by which the padded member 12 is affixed to the support member 50 is not critical as long as the attachment means 200 does not interfere with the natural suppleness of the outer covering 38 or interfere with the padded member 12 conforming to the facial configuration of the user. The attachment means 200 may be placed in a continuous or intermittent pattern along the upper surface 60 of the support member 50 and/or on a bottom surface of the outer covering 38 that is adjacent to the upper surface 60.

For example, the attachment means 200 may fixedly attach the padded member 12 to the support member 50. Examples of such means for attachment include adhesives,

such as hot melt adhesives; pressure sensitive adhesives; double sided tapes; contact cohesives; screws; brads; rivets; tabs in the support device 50 secured to loops in the outer covering 38, (not shown); and combinations thereof. Desirably, the attachment means 200 is a pressure sensitive adhesive such as a double sided tape, (available from Minnesota Mining and Manufacturing, product number 407) or a contact cohesive. Alternatively, the attachment means 200 may removably affix the padded member 12 to the support member 50. Examples of such means for removable attachment include snaps, buttons, hook and loop fasteners, and weakly bonded cohesives. Desirably, when the attachment means 200 is a hook and loop attachment, the hook is a micro hook material affixed to the support device 50 and the bottom surface 22 of the padded member 12 is capable of engaging the micro hook material.

Having described the invention in detail, those skilled in the art will appreciate that modifications may be made to the various aspects of the invention without departing from the scope and spirit of the invention disclosed and described herein. It is, therefore, not intended that the scope of the invention be limited to the specific embodiments illustrated and described but rather it is intended that the scope of the present invention be determined by the appended claims and their equivalents. Moreover, all patents, patent applications, publications, and literature references presented herein are incorporated by reference in their entirety for any disclosure pertinent to the practice of this invention.